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Indian Standard

FOOD HYGIENE — MICROBIOLOGICAL CRITERIA — PRINCIPLES FOR ESTABLISHMENT AND APPLICATION

ICS 67.020

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

July 1998

Price Group 2

Food Hygiene Sectional Committee, FAD 45

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Food Hygiene Sectional Committee had been approved by the Food and Agriculture Division Council.

Safety of food is principally assured by control at the source, product design and process control, and the application of good hygienic practices during production, processing (including labelling), handling, distribution, storage, sale, preparation and use, in conjunction with the application of the HACCP system [*see* IS 15000:1998 'Food hygiene — Hazard analysis and critical control point (HACCP) — System and guidelines for its application']. The preventive approach offers more control than microbiological testing because the effectiveness of microbiological examination to assess the safety of foods is limited.

Microbiological criteria should be established according to these principles and be based on,scientific analysis and advice, and where sufficient data are available, a risk analysis appropriate to the foodstuff and its use. Microbiological criteria should be developed in a transparent fashion and meet the requirements of fair trade. They should be reviewed periodically for relevance with respect to emerging pathogens, changing technologies and new understanding of science.

Microbiological criteria may be used to formulate design requirements and to indicate the required microbiological status of raw materials, ingredients and end-products at any stage of the food chain as appropriate. They may be relevant to the examination of foods, including raw materials and ingredients, of unknown or uncertain origin or when other means of verifying the efficacy of HACCP-based systems and good hygienic practices are not available. Generally, microbiological criteria may be applied to define the distinction between acceptable and unacceptable raw materials, ingredients, products, lots, by regulatory authorities and/or food business operators. Microbiological criteria may also be used to determine that processes are consistent with the general principles of food hygiene [*see* IS 2491:1998 'Food hygiene — General principles — Code of practice (*second revision*)'].

Microbiological criteria are not normally suitable for monitoring critical limits as defined in IS 15000:1998. Monitoring procedures must be able to detect loss of control at a critical control point (CCP). Monitoring should provide this information in time for corrective actions to be taken to regain control before there is a need to reject the product. Consequently, on-line measurements of physical and chemical parameters are often preferred to microbiological testing because results are often available more rapidly and at the production site. Moreover, the establishment of critical limits may need other considerations than those described in this standard.

To provide the needed guidelines, this Indian Standard has been formulated based on the Codex Standard Principles for the establishment and application of microbiological criteria for foods CAC/RCP-22 (1997), and is identical to it.

The standard is subject to the provisions of the appropriate food safety legislations, such as *Prevention of Food Adulteration Act,* 1954 and Rules framed thereunder.

Indian Standard

FOOD HYGIENE — MICROBIOLOGICAL CRITERIA — PRINCIPLES FOR ESTABLISHMENT AND APPLICATION

1 SCOPE

This standard provides guidance on the establishment and application of microbiological criteria for foods at any point in the food chain from primary production to final consumption.

2 REFERENCES

The Indian Standards listed below contain provisions which through reference in this text, constitute provision of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

IS No.	*Title*
2491 : 1998	Food hygiene — General principles — Code of practice (*second revision*)
15000 : 1998	Food hygiene — Hazard analysis and critical control point (HACCP) — System and guidelines for its application

3 DEFINITIONS

For the purpose of this standard the following definition shall apply.

3.1 Microbiological Criteria

Acceptability of a product or a food lot, based on the absence or presence, or number of microorganisms including parasites, and/or quantity of their toxins/metabolites, per unit(s) of mass, volume, area or lot.

4 PRINCIPLES FOR ESTABLISHING AND APPLYING MICROBIOLOGICAL CRITERIA — GENERAL CONSIDERATIONS

4.1 A microbiological criterion should be established and applied only where there is a definite need and where its application is practical. Such need is demonstrated, for example, by epidemiological evidence that the food under consideration may represent a public health risk and that a criterion is meaningful for consumer protection, or as the result of a risk assessment. The criterion should be technically attainable by applying good manufacturing practices (codes of practice).

4.2 To fulfil the purpose of a microbiological criterion, consideration should be given to:

a) the evidence of actual or potential hazards to health;

b) the microbiological status of the raw material(s);

c) the effect of processing on the microbiological status of the food;

d) the likelihood and consequences of microbial contamination and/or growth during subsequent handling, storage and use;

e) the cost/benefit ratio associated with the application of the criterion; and

f) the intended use of the food.

4.3 Components of Microbiological Criteria for Foods

4.3.1 A microbiological criterion consists of:

a) a statement of the microorganisms of concern and/or their toxins/metabolites and the reason for that concern (*see* **4.4**);

b) the analytical methods for their detection and/or quantification (*see* **4.5**);

c) microbiological limits considered appropriate to the food at the specified point(s) of the food chain (*see* **4.6**);

d) a plan defining the number of field samples to be taken, size of the analytical unit (*see* **4.7.1** and **4.7.2**); and

e) the number of analytical units that should conform to these limits (*see* **4.7.3**).

4.3.2 A microbiological criterion should also state:

a) the food to which the criterion applies,

b) the point(s) in the food chain where the criterion applies, and

c) any actions to be taken when the criterion is not met.

4.3.3 When applying a microbiological criterion for assessing products, it is essential, in order to make the best use of money and manpower, that only appropriate tests be applied to those foods and at those points in the food chain that offer maximum benefit in providing the consumer with a food that is safe and suitable for consumption.

4.4 Microorganisms of Concern

4.4.1 For the purpose of this standard, the microorganisms, parasites and their toxins/metabolites of concern in a particular food include bacteria, viruses, yeasts, moulds, and algae, parasitic protozoa and helminths and their toxins/metabolites.

4.4.2 The microorganisms included in a criterion should be widely accepted as relevant - as pathogens, as indicator organisms or as spoilage organisms- to the particular food and technology. Organisms whose significance in the specified food is doubtful should not be included in a criterion.

4.4.3 The mere finding, with a presence-absence test, of certain organisms known to cause foodborne illness, such as *Clostridium perfringens, Staphylococcus aureus* and *Vibrio parahaemolyticus* does not necessarily indicate a threat to public health.

4.4.4 Where pathogens can be detected directly and reliably, consideration should be given to testing for them in preference to testing for indicator organisms. If a test for an indicator organism is applied, there should be a clear statement whether the test is used to indicate unsatisfactory hygienic practices or a health hazard.

4.5 Microbiological Methods

4.5.1 Whenever possible, only methods for which the reliability (accuracy, reproducibility, inter-and intra-laboratory variation) has been statistically established in comparative or collaborative studies in several laboratories should be used. Moreover, preference should be given to methods which have been validated for the commodity concerned preferably in relation to reference methods. While methods should be most sensitive and reproducible for the purpose, methods to be used for in-plant testing might often sacrifice to some degree of sensitivity and reproducibility in the interest of speed and simplicity. They should, however, have been proved to give a sufficiently reliable estimate of the information needed.

4.5.2 Methods used to determine the suitability for consumption of highly perishable foods, or foods with a short shelf-life, should be chosen wherever possible so that the results of microbiological examinations are available before the foods are consumed or exceed their shelf-life.

4.5.3 The microbiological methods specified should be reasonable with regard to complexity, availability of media, equipment, ease of interpretation, time required and costs.

4.6 Microbiological Limits

4.6.1 Limits used in criteria should be used on microbiological data appropriate to the food and should be applicable to a variety of similar products. They should therefore be based on data gathered at various production establishments operating under good hygienic practices (*see* IS 2491) and applying the HACCP system (*see* IS 15000).

4.6.2 In the establishment of microbiological limits, any changes in the microflora likely to occur during storage and distribution, such as decrease or increase in numbers should be taken into account.

4.6.3 Microbiological limits should take into consideration the risk associated with the microorganisms, and the conditions under which the food is expected to be handled and consumed. Microbiological limits should also take account of the likelihood of uneven distribution of microorganisms in the food and the inherent variability of the analytical procedure.

4.6.4 If a criterion requires the absence of a particular microorganism, the size and number of the analytical unit as well as the number of analytical sample units should be indicated.

4.7 Sampling Plans, Methods and Handling

4.7.1 A sampling plan includes the sampling procedure and the decision criteria to be applied to a lot, based on examination of a prescribed number of sample units and subsequent analytical units of a stated size by defined methods. A well-designed sampling plan defines the probability of detecting microorganisms in a lot, but it should be borne in mind that no sampling plan can ensure the absence of a particular organism. Sampling plans should be administratively and economically feasible. In particular, the choice of sampling plans should take into account the following:

a) risks to public health associated with the hazard,

b) the susceptibility of the target group of consumers,

c) the heterogeneity of distribution of microorganisms where variables sampling plans are employed, and

d) the acceptable quality level and the desired statistical probability of accepting a non-conforming lot.

NOTE — For many applications, 2-or 3-class attribute plans may prove useful.

4.7.2 The statistical performance characteristics or operating characteristics curve should be provided in the sampling plan. Performance characteristics provide specific information to estimate the probability of accepting a non-conforming lot. The sampling method should be defined in the sampling plan. The time between taking the field samples and analysis should be as short as reasonably possible, and during transport to the laboratory the conditions, such as temperature should not allow increase or decrease of the numbers of the target organism, so that the results reflect, within the limitations given by the sampling plan, the microbiological conditions of the lot.

4.7.3 The number and size of analytical units per lot tested should be as stated in the sampling plan and should not be modified. However, a lot should not be subjected to repeated testing in order to bring the lot into compliance.

4.8 Reporting

The test report shall give the information needed for complete identification of the sample, the sampling plan, the test method, the results and, if appropriate, their interpretation.